Serial No.: 10/552,160 Amendment dated Feb. 23, 2009

Reply to final OA of Nov. 21, 2008 Docket No.: 66386-371

## <u>REMARKS</u>

By this Amendment the specification has been amended to change the reference designator for the referenced passages (see also the concurrently filed Submission of Replacement Drawing Sheet), claims 1-26, 28 and 30 have been amended to better define the invention, and claim 29 has been canceled. Entry is requested.

In the outstanding final Office Action the examiner has rejected claim 28 under 35 U.S.C. 102(b) as being anticipated by Brain '956, and he has rejected claim 29 under 35 U.S.C. 103(a) as being unpatentable over Brain '956 in view of Brain '790.

Brain '956 and Brain '790 have been discussed previously. In Brain '790 an embodiment is shown which has two inflatable bellows. However, they are provided on the top surface of the mask portion and are not provided on a top surface of the inflatable cuff portion. In fact, Brain '790 discloses a mask which does not have a top face of the inflatable cuff since the inflatable cuff portion is purely arranged below the mask and does not have any portion on the top face of the mask. Thus, no combination of Brain '790 with Brain '956 would suggest the invention as defined in amended claim 28.

The examiner has rejected claims 1-10, 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over Collins in view of Pagan, he has rejected claims 11 and 14-17 under 35 U.S.C. 103(a) as being unpatentable over Collins in view of Pagan and Brain '790, and he has

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rejected claims 18-26 under 35 U.S.C. 103(a) as being unpatentable over

Collins in view of Pagan and Hicks et al.

These rejections are without merit.

Collins discloses a mask which comprises an airway tube and a

mask portion. The airway tube and mask portion are injection moulded

as a single component. An inflatable cuff is fastened to the mask portion

via gluing after the injection moulding process.

Pagan discloses a mask portion which is injection moulded and the

airway tube is fastened to the mask portion after the injection moulding

process. Pagan, however, discloses that the inflatable cuff portion of the

mask portion is manufactured by first injection moulding a solid ring at

the periphery of the mask portion, then heating the ring and blow

moulding the walls of the inflatable cuff portion. The peripheral edge of

the walls of the inflatable cuff portion is fastened to the mask portion via

gluing or welding in order to close the inflatable cuff portion.

The examiner asserts that a combination of Collins and Pagan will

lead to the invention as claimed in claim 1. However, it is believed that a

combination of Collins and Pagan will result in a mask where the airway

tube and the mask portion are injection moulded in a first mould, where

after the walls of the inflatable cuff portion are blow moulded as disclosed

in Pagan.

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The mask disclosed by the current application is, however, quite different in that the walls of the inflatable cuff portion are manufactured by an injection moulding process in a closed mould. In this way, the wall thickness of the walls of the inflatable cuff portion can be precisely controlled by the void in the mould. Since the wall thickness of the inflatable cuff portion can be controlled precisely, the form of the inflated inflatable cuff portion can be very accurately controlled. For example, those areas which should "bulge" more can be made thinner than those portions which should maintain a more controlled shape. Those areas which should be stiff can be made thicker.

In the specification, it is, for example, described that the wall thickness of the top surface of the inflatable cuff portion could be made thicker whereas the wall thickness of the bottom surface of the inflatable cuff portion is made thinner. Another example given in the specification is that some areas of the top surface of the inflatable cuff portion have a thinner wall thickness than others. This causes these thinner areas to bulge upwards when inflated. These areas then provide the "inflatable bellows" which are described in combination with figures 4A-4D. See for example page 18, lines 1-16, of the PCT application as filed.

By manufacturing the inflatable cuff portion via injection moulding instead of blow moulding, a number of advantages are therefore presented. These advantages are not described in either Collins or Pagan whereby the person of ordinary skill in the art will not be inspired to form

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the inflatable cuff portion by injection moulding. Furthermore, it can be noted that the mould necessary to form the inflatable cuff portion via injection moulding instead of blow moulding is much more complicated since it comprises many more moving parts. Therefore, a person of ordinary skill in the art would not have found it obvious to manufacture the inflatable cuff portion via injection moulding.

other patents which disclose manufacturing a portion of an inflatable cuff portion via injection moulding, for example, Brain '790. However, these patents disclose injection moulding an open inflatable cuff portion which is then glued onto a larger mask portion in order to close the inflatable portion. The problems with the mould of the current invention are not present in the case where an open inflatable cuff portion is injection moulded.

The applicants assert that the presented claims define an invention which is new and novel over the prior art in that the mask portion, the inflatable cuff portion and the airway tube are all manufactured as a single integrated element and in a single closed mould.

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Favorable reevaluation is requested.

Respectfully submitted,

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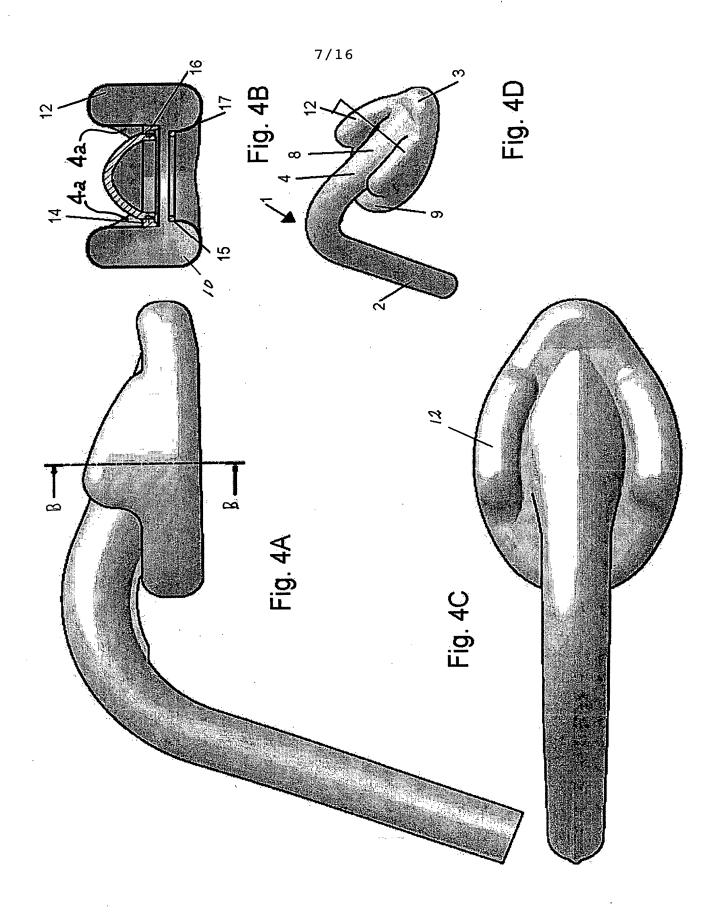
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